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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.    |
|--|-------------|----------------------|---------------------|---------------------|
| 10/697,613   | 10/29/2003  | Gerhard Kastenhofer  | 1001.1291103        | 9625                |
| 28075  | 7590        | 03/18/2008           | EXAMINER            |                     |
| CROMPTON, SEAGER & TUFTE, LLC<br>1221 NICOLLET AVENUE<br>SUITE 800<br>MINNEAPOLIS, MN 55403-2420 |             |                      |                     | VU, QUYNH-NHU HOANG |
| ART UNIT   |             | PAPER NUMBER         |                     |                     |
| 3763   |             |                      |                     |                     |
|  |             | MAIL DATE            |                     | DELIVERY MODE       |
|  |             | 03/18/2008           |                     | PAPER               |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                      |
|------------------------------|------------------------|----------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>  |
|                              | 10/697,613             | CASTENHOFER, GERHARD |
|                              | <b>Examiner</b>        | <b>Art Unit</b>      |
|                              | QUYNH-NHU H. VU        | 3763                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 February 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 11-21 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 11-21 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/5/08.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

Amendment filed on 02/29/08 has been entered.

Claims 11-21 are present for examination.

Applicant's arguments with respect to claims 11-21 have been considered but are moot in view of the new ground(s) of rejection claims 11-17, claims 18-21 are same as previous rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman et al. (US 5,728,063) in view of Fontirroche et al. (US 5,538,510) (cited from IDS), Ross et al. (US 5,395,866).

Preissman discloses a catheter comprising: a first catheter tube 102 having at least two superposed layers of materials, an inner layer 108, an outer layer 110; secured together with a polymeric mediator layer 112 or 114 layer (reinforcement layer 112, 114 composed of polymeric fiber, col. 7, lines 15-22); wherein the mediator layer adhered to both the inner layer and outer layer (the inner tubular members as a laminate structure comprising outer layer and inner layer or coating, see col. 7, lines 7-14, therefore, the media layer 112, 114 adhered to inner and outer layer) and with mechanical properties differing from one another, a guide wire lumen 108 in the first catheter tube, and a balloon 106 sealing surrounding the first catheter tube; the outer layer 110 comprises a polymer, i.e. polyamide (col. 7, lines 54-60) and forms an outer surface of the first catheter tube; wherein the first catheter tube includes a distal end and the outer layer extends to the distal end of the first catheter tube (Fig. 4). A second catheter tube 104 disposed about the first catheter tube; wherein a proximal end of balloon is connected to a distal end of the second tube, and a distal end of the balloon is connected to a distal end of the first tube.

Art Unit: 3763

Preissman further discloses the inner layer 108 comprises of polymer or the like (col. 7, lines 5-15); the mediator layer made of polymeric fibers (col. 5, lines 15-30). Preissman does not specifically disclose the inner layer comprises high density polyethylene; the mediator layer comprises low density polyethylene.

Fontirroche discloses that the inner layer can provide a high density polyethylene, low friction coefficient (col. 3, lines 9-20).

Ross discloses that the suitable reinforcement material, which is mediator layer 112, 114, can be polyethylene teraphthalate filament (col. 6, lines 1-6) to provide the low friction to a guide wire or inner catheter. It is noted that polyethylene teraphthalate filament is a low density polyethylene.

Crocker (US 5,344,402) is an evidence to show that polyethylene teraphthalate filament is a low density polyethylene (col. 8, lines 59-61).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to try the high density polyethylene of Fontirroche and the low density polyethylene of Ross in an attempt to provide an improved product of Preissman, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. In turn, the inner layer made of high density polyethylene to provide low friction to a guide wire or inner catheter, and the media layer made of low density polyethylene to enhance the flexibility and prevent kinking of catheter.

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman et al. (US 5,728,063) in view of Gold et al. (US 4,636,346).

Regarding claims 18-21, Preissman discloses a catheter comprising: a first catheter tube 102 comprising: an outer most layer 110 comprising a polymer having a first coefficient of friction; an inner most layer 108 coextensive with the outermost layer 110 and forming a lumen; the inner most layer 108 comprises a polymer having a second coefficient; a middle layer 112, 114 disposed between the outermost layer 110 and the innermost layer 108 and affixing the outermost layer to the innermost layer; a second tube 104 disposed about a portion of the first tube; and a balloon 106 with a distal end sealing surrounding the outermost layer of the first tube and a proximal end sealingly surrounding the second tube.

Preissman discloses that the inner most layer formed of lubricious polymer ect... (col. 7, lines 7-14); the outer most layer formed of soft thermoplastic such as polyamide (col. 7, lines 54-60, col. 10, lines 42-45). Preissman does not clearly disclose that the inner most layer having a second coefficient of friction which is less than the first coefficient of friction of outer most layer.

Gold discloses that a tube 22 comprising an outermost layer 33 comprising a polymer (col. 4, lines 57-67), such as low density polyethylene (high coefficient of friction); an inner most layer 31 is made of superior lubricity material, copolymers of ethylene (col. 4, lines 12-25). It is noted that if material with superior high lubricity, it will have low coefficient of friction.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Preissman with a different coefficient of friction, as taught by Gold, in order to provide an improved intravascular guiding catheter and resistant to kinking.

Furthermore, one skill in the art would recognize that the outermost layer made of low coefficient of friction to easy moving within the vessel or prevent the guide wire clogging in the guide wire lumen of the catheter tube (Applicant Admitted Prior Art, page 2, lines 18-27).

#### ***Response to Arguments***

Applicant's arguments filed 2/29/08 have been fully considered but they are not persuasive.

1. Applicant argues that Preissman does not teach that the middle layer/reinforcement layer 112 or 114 affixed the soft outer layer 110 to the inner tubular member 108.

In response, Preissman clearly discloses that the inner tubular members as a laminate structure comprising: an outer layer 110 and an inner layer 108. While the middle layer/reinforcement layer 112, 114 disposed in between the inner layer 108 and outer layer 110. Therefore, the middle layer/reinforcement layer 112 or 114 affixed the soft outer layer 110 to the inner tubular member 108.

Additionally, according to [www.answers.com](http://www.answers.com), it defines that "affix" is to secure to something or attach, to join one thing to another, connect, coupled. The middle layer/reinforcement layer 112, 114 of Preissman is attached/connected/coupled to the inner 108 and outer layer 110.

2. Applicant argues that the teaching of Gold would not apprise one of skill in the art to the notion that the reinforcement layer 112, 14 affixes the soft outer layer 110 to the inner tubular member 108.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Additionally, Preissman clearly discloses this matter as discussed above. Gold teaches the benefits of provided materials of outer and inner layer. Therefore, one skill in the art would combine Pressman in view of Gold to improve his products.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763